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| 21839 | 7590 | 11/21/2003 | EXAMINER | |
| BURNS DOANE SWECKER & MATHIS L L P | | | NICHOLS, CHRISTOPHER J | |
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1647

DATE MAILED: 11/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856,576

Applicant(s)

ERIKSSON, PETER

Examiner

Christopher Nichols, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42, 53 and 59-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42, 53, and 59-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Status of Application and Claims

1. The Amendment and Response filed 10 October 2003 has been received and entered in full. Claims **1-41, 43-52**, and **54-58** have been cancelled. Claims **42, 53**, and **59** have been amended. Claims **60-72** have been added.
2. The Examiner acknowledges that the cancellation of the above listed claims does not mitigate in any way, shape, or form, Applicant's right to pursue additional subject matter in continuation, continuation-in-part, and/or divisional applications pursuant to 35 U.S.C. §120 and §121.
3. The Applicant asserts that the claims are to be considered free of the art listed at the end of the previous Office Action (10 June 2003). The Examiner respectfully notes that the Applicant is incorrect in this conclusion. The art listed at the end of the previous Office Action was "art of note"; no statement of any claims being "free of the art" was made or should be implied. The art listed at the end of an Office Action by an Examiner should be taken into consideration as "art of note". The art so listed is pertinent to the instant application, in so far as it may contain limitations from which grounds of rejection may be made, it may provide definitions for terms, teach limitations as to support or rejection enablement, or provide useful background information. Further, any art listed, especially US Patent Application Publications [35 U.S.C. §122(a)] with later filing dates, may be listed by the Examiner to put forth Applications which contain or claim similar subject matter for the Applicant's consideration. At no time should claims be considered "free of the art" unless explicitly stated by the Examiner. While the claims

are not currently rejected under 35 U.S.C. §102 or §103 over the references listed at the bottom of page 11 of the previous Office Action, the claims have not been deemed free of this prior art.

Withdrawn Objections And/Or Rejections

4. The Objection to the Oath/Declaration as set forth at pp. 3 ¶3 in the previous Office Action (10 June 2003) is *withdrawn* in view of the replacement Oath/Declaration filed 10 October 2003.
5. The Objection to the Drawings as set forth at pp. 3 ¶4 in the previous Office Action (10 June 2003) is *withdrawn* in view of the formal drawings filed 10 October 2003.
6. The Objection to the Claims as set forth at pp. 3 ¶5 in the previous Office Action (10 June 2003) is *withdrawn* in Applicant's amendments (10 October 2003).
7. The Rejection of claim **42** under 35 U.S.C. §112 ¶1 as set forth at pp. 3-6 ¶6-12 in the previous Office Action (10 June 2003) is *withdrawn* in view of Applicant's amendments (10 October 2003).
8. The Rejection of claims **53** and **59** under 35 U.S.C. §112 ¶2 as set forth at pp. 9-10 ¶23 in the previous Office Action (10 June 2003) is *withdrawn* in view of Applicant's amendments (10 October 2003).
9. The Rejection of claims **42**, **53**, and **59** under 35 U.S.C. §102(a) as set forth at pp. 10 ¶24 in the previous Office Action (10 June 2003) is *withdrawn* in view of Applicant's perfection under 35 U.S.C. §119(a-d) making Sweden (9804064) the Applicant's priority document. Applicant is correct and the rejection is *withdrawn* as now improper (10 October 2003).

Maintained Objections And/Or Rejections

10. Claims **53, 59, and 62-72** are rejected under 35 U.S.C. §112 ¶1, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons as set forth in the previous Office Action at pp. 6-9 ¶13-22.

11. Applicant traverses this rejection in the Response and Amendment filed 10 October 2003 on the following grounds: **(a)** the Examiner has appeared to raise the standard of patentability to prove safety and efficacy in humans and pursuant to *In re Brana*, 24 U.S.P.Q. 2d 1436, this is an improper grounds of rejection, **(b)** Applicant has provided *in vivo* animal data which constitutes a working example and a constructive reduction to practice, and **(c)** Applicant has provided additional evidence to demonstrate that the proliferation shown in the Specification is specific to neurons and thus supports the claims.

12. The Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

13. On "**(a)**", no requirement for human trials or Phase II testing was set for in the previous Office Action, therefore the findings in *In re Brana*, 24 U.S.P.Q. 2d 1436 are not applicable to the instant application. The method was rejected on grounds of lack of enablement.

14. On "**(b)**", the Examiner acknowledges that the filing of a patent application constitutes a constructive reduction to practice but this is not at issue. The Examiner set forth reasons that the animal data provided in the instant application is insufficient to support the claims for the reasons in the previous Office Action.

15. On “(c)”, the data insufficient to overcome the rejection because any evidence submitted to traverse a rejection or objection on a basis not otherwise provided for must be by way of an oath or declaration under 37 CFR §1.132. Therefore the Appendix submitted with the Amendment and Response is improper. All addition data which is not contained in the Specification must be submitted in the form of publication or Declarations pursuant to 37 CFR §1.131. Therefore the information contained in the Appendix has been entered but not taken into consideration.

16. The rejection of claims 53, 59, and 62-72 under 35 U.S.C. §112 ¶1 is hereby maintained.

17. Claims **42** and **60** are rejected under 35 U.S.C. §102(b) as anticipated by Almazan *et al.* (August 1985) “Epidermal Growth Factor and Bovine Growth Hormone Stimulate Differentiation and Myelination of Brain Cell Aggregates in Culture.” Developmental Brain Research 21: 257-264 for the reasons as set forth in the previous Office Action at pp. 10 ¶25.

18. The Examiner first notes that Applicant is correct, Almazan *et al.* is from Vol. 21 not Vol. 353 of Developmental Brain Research.

19. Applicant traverses this rejection in the Response and Amendment filed 10 October 2003 on the following grounds: **(a)** claim 42 has been amended to read “progenitor and stem cells” not cell aggregates.

20. The Applicant’s arguments have been taken into consideration and are not found persuasive for the following reasons.

21. The term cell aggregates in the art is a general term that refers to a composition of cells, usually derived from fetal or embryonic sources, that contain progenitor and stem cells as well as

other cell types. It is also noted that fetal tissue is almost exclusively stem cells as well as progenitor cells [see Eckenhoff & Rakic (August 1988) "Nature and Fate of Proliferative Cells in the Hippocampal Dentate Gyrus During the Life Span of the Rhesus Monkey." The Journal of Neuroscience 8(8): 2729-2747 (IDS) and US 5750376]. Thus Almazan *et al.* teaches the isolation of cell aggregates from fetal rats (15-16 days gestation) which contained stem cells as well as progenitor cells, thus meeting the limitations of claims 42 and 60 (pp. 258).

22. The rejection of claims 42 and 60 under 35 U.S.C. §102(b) is hereby maintained.

23. Claims 42, 60, and 61 are rejected under 35 U.S.C. §102(b) as anticipated by US 5,750,376 for the reasons as set forth in the previous Office Action at pp. 11 ¶26.

24. Applicant traverses this rejection in the Response and Amendment filed 10 October 2003 on the following grounds: (a) US 5,750,376 does not teach the use of somatotropin, the only definition of "a growth hormone".

25. The Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

26. On "(a)", the claims are presented read "a growth hormone", which includes but is not limited to somatotropin. Thus the Applicant is incorrect in their interpretation. The plain meaning of "a growth hormone" can pertain to any of a large genus of compounds and is not strictly limited to somatotropin as asserted (see Col. 16 lines 53-67). This is also evident from the fact that the instant claim 59 recites the limitation of "a growth hormone" which were to mean in the most strict interpretation as a single molecule of somatotropin, which, if so read, would further support the rejection under 35 U.S.C. §112 ¶1 as set forth in the previous Office Action

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and maintained herein. In addition, US 5,750,376 teaches that “growth hormone” may be used to practice the methods taught therein (Col. 20 line 54).

27. Further concerning the limitation of “human central nervous system” in newly added claim 61, US 5,750,376 teaches that the method can be practiced with mammalian tissue including humans thus meeting the limitations of claim 61 as well as 42 and 60 (Col. 13 lines 23-33).

28. The rejection of claims 42, 60, and 61 under 35 U.S.C. §102(b) is hereby maintained.

Summary

29. Claims 42, 53, and 59-72 are hereby rejected.

30. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

31. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
November 17, 2003



ELIZABETH KEMMERER
PRIMARY EXAMINER